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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,799	11/30/2001	Siu Man L. Cowan	22112 (3)	9508

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03/21/2003

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EXAMINER

PRYOR, ALTON NATHANIEL 7

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/020,799

Applicant(s)
Cowan et al

Examiner
Alton Pryor

Art Unit
1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 26, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-12, and 17-22 is/are rejected.
- 7) ☒ Claim(s) 4-7 and 13-16 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections under 35 U.S.C. 102(b)

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3,8,12,17-19,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Humphreys et al (US 5385685; 1/31/95). Humphreys teaches a liquid detergent composition comprising 5-70% glyceroglycolipid compound, 0.01-5% enzyme, 0.1-15% enzyme stabilizer, and the balance water which would fall within the instant range of 20-80%. Humphreys teaches 3-(octyloxy)-2-hydroxypropyl-beta-D-galactopyranoside as the C8-glycopyranoside. See column 3 line 5 -column 4 line 19, column 9 lines 37-59, claim 1. The instant claims are directed to a stable formulation useful for aerosol delivery to the respiratory tract of a patient. Regarding the stability of the prior art composition, the prior art composition is stable since it employs enzyme stabilizers. Regarding the instant composition claims to the use of the instant composition in aerosol delivery to the respiratory tract of a patient, this is unpatentable since a statement to intended use in a composition claim adds no significance to the composition being claimed.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Chaplygina et al (SU 818619; 4/7/81). Chaplygina teaches a composition comprising 20-25 % protein hydrolysate

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Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 511116806, 10/14/76. JP '806 teaches a water system liquid detergent comprising a protein, sugars (glucose, trehalose), solvents (water, ethanol). See abstract. JP '806 does not teach the composition comprising 10-100% water. However, JP '806 does teach that water is present. One having ordinary skill in the art at the time the invention was made would have been expected to determine the optimum amount of water. One having ordinary skill in the art would be motivated to do this in order to make the most effective detergent.

Other Matters

In claim 2 line 1 examiner suggests that applicant deletes "suspension" and insert --- formulation ---. Claim 1 from which claim 2 depends is drawn to a formulation rather than to a suspension.

Claim Objection

Claims 4-7,13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant comprising protein in suspension and the protein being a hormone or cytokine or insulin or Factor VIII.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

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(protein), 20-30 % glucose, 4-6 % ethanol, 1-1.4 % peppermint extract, 0.08-0.12 % disodium phosphate, 0.03-0.05 % saccharin and the balance water which would fall within the instant range of 10 -100 % water. See abstract.

Claim Rejections under 35 U.S.C. 103(a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

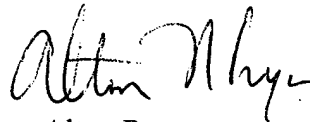
4. Claims 9-11,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humphreys et al as applied to claims 1-3,8,12,17-19,21 above.

See 102(b) rejection above. Humphreys teaches all that is recited in claims 9-11,20 except for an example wherein polyethylene glycol and/or ethanol is / are used. However, Humphreys does teach that a number of other ingredients, including polyethylene glycol and/or ethanol, can be added to his composition. See column 18 lines 40-68. It would have been obvious to one having ordinary skill in the art to make the prior art composition comprising ethanol and / or polyethylene glycol since Humphreys makes the suggestion. With respect to the instant amounts of ethanol, one having ordinary skill in the art would have been expected to determine the optimum amounts through routine experimentation. One would have been motivated to do this in order to develop the most effective liquid detergent.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Alton Pryor

**ALTON N. PRYOR
PRIMARY EXAMINER**

Primary Examiner, AU 1616

3/15/03
